Department of the Navy
Human Research Protection Program

Education and Training Policy for Research Ethics and the Responsible Conduct of Research

1. Purpose

To provide policy for Department of the Navy (DON) commands, personnel, and DON-supported institutions on how to meet Department of Defense and DON requirements for research ethics training.

This policy focuses on the requirements for human subject protection training and will be updated as additional policy on research ethics training is implemented.

2. Background

In response to a DoD-wide initiative to raise awareness of and improve compliance with human research protections, all Department of the Navy Human Research Protection Program (DON HRPP) personnel who conduct, review, approve, support, manage, or oversee research are required to complete initial and continuing research ethics training.

In 2000, the National Institutes of Health (NIH) implemented a training requirement for investigators and key personnel and established a program specific to NIH-supported research. The NIH also included training requirements for the responsible conduct of research (RCR) established under the auspices of the Office of Research Integrity (ORI) within the Department of Health and Human Services (DHHS).

3. Responsible Conduct of Research (RCR) Core Areas

The Public Health Service (PHS) policy for RCR outlines nine (9) core areas for initial and continuing education. These are referred to in DoDD 3216.2, "Protection of Human Subjects."

a. Data acquisition, management, sharing and ownership
b. Mentor/trainee responsibilities
c. Publication practices and responsible authorship
d. Peer review
e. Collaborative science
f. Human subjects
g. Research involving animals
h. Research misconduct
i. Conflict of interest and commitment

4. DON Policy: Research Ethics Education Program Requirements

All personnel who conduct, review, approve, support, manage, or oversee research must complete initial training. All personnel then must complete three to six hours of research-ethics continuing training every three years, depending on their roles and responsibilities in human subject research.

To meet DON requirements for research ethics training, institutions may use their own institutional program or use existing programs that meet the requirements in this policy.

Whether institutions use already-available programs or create their own, the training program must meet the following requirements.

a. Training programs must include initial and continuing programs.
b. Content must be appropriate to the individuals' level of involvement and their duties and responsibilities.
c. Program content, learning objectives, speaker qualifications, attendance, etc., must be documented clearly.
d. Training programs must evaluate attendees' knowledge, learning, or meeting of the objectives.
e. Attendees must have an opportunity to evaluate program content and speakers.
f. Plans for continually evaluating and refining training needs.

The Collaborative Institutional Training Initiative (CITI), a web-based, self-contained course oriented to both biomedical and social behavioral research, meets these requirements. See enclosure (1). CITI also offers a number of training modules in several foreign languages through its international sites.

Commands are encouraged to provide annual education and training specific to their needs that supplements these requirements.

Note: The NIH web-based training program, "Human Participant Protections Education for Research Teams," does not meet DON HRPP training requirements as it is specific to NIH policies and procedures and has a biomedical focus.

5. Human Subject Protection Training Requirements by Role and Responsibility

a. Initial Training

All personnel who conduct, review, approve, support, manage, or oversee research must complete initial training. Individuals serving in several roles must complete the most comprehensive requirements. See enclosure (1) for specific training requirements and deadlines for completion.

b. Continuing Training

All personnel must complete three to six hours of research-ethics continuing training every three years depending on their roles and responsibilities in human subject research. Only training offerings directly relevant to research ethics, human subject protections, and the responsible conduct of research meet DON HRPP criteria for continuing training. Individuals may choose among many offerings to meet requirements. See enclosure (2).

6. Training Documentation

a. Individual Responsibility

Individuals are responsible for keeping accurate records of their initial and continuing training. PIs and key research personnel must provide verification or copies of training records when submitting research protocols.

b. Institution Responsibility

Institutions are responsible for verifying and storing training documents (electronic and/or paper copy). Institutions should verify whether PIs have met training requirements

prior to accepting research protocols for scientific or ethical review and whether all other personnel have met the training requirements appropriate to their role and level of responsibility.

c. DON HRPP Responsibility

DON HRPP maintains central electronic documentation for all personnel using the CITI program. The DON HRPP will monitor and oversee institutions' education and training programs.

7. References

a. DoD Directive 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," March 25, 2002

b. SECNAVINST 3900.39D, "Human Research Protection Program," November 3, 2006

c. National Institutes of Health (NIH) Notice: OD-00-039 of June 5, 2000 (Revised August 25, 2000)

d. Office of Research Integrity, PHS Policy of Instruction in the Responsible Conduct of Research (RCR) – December 1, 2000 (Pending)

Department of the Navy Human Research Protection Program
Collaborative Institutional Training Initiative (CITI)

If institutions choose CITI for initial and continuing training, see below for requirements.

- After registering, individuals select the appropriate "Research Role" (Learner Group) and "Focus" (Course) of modules – biomedical or social-behavioral research (SBR)
- Individuals must receive a score of 80% to receive a CITI-generated completion certificate.
- See CITI at https://www.citiprogram.org/default.asp

Research Role	Initial Training	Continuing Training
1. Navy Surgeon General (SG), Chief of Naval Research (CNR) and Command Leadership (Institutional Signatory Officials, Commanding Officers , Executive Officers, Officers-In-Charge) **Estimated Time: 1 hour** Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 60 days of assignment.	**BIOMEDICAL FOCUS** 1. History & Ethical Principles 2. Defining Research with Human Subjects – Social Behavioral Research (SBR) 3. SBR for Biomedical Researchers 4. Department of the Navy HRPP Module for Senior Navy and Command Leadership **SOCIAL-BEHAVIORAL FOCUS** 1. History & Ethical Principles – SBR 2. Defining Research with Human Subjects – SBR 3. Assessing Risks - SBR 4. Department of the Navy HRPP Module for Senior Navy and Command Leadership	**Continuing training requirement:** **3 hours every 3 years** Options: 1. CITI Program: 3 modules of your choice from refresher modules or other modules you have not taken 2. Three (3) hours of equivalent continuing training

Research Role	Initial Training	Continuing Training
2. Directors, Department Chairs, Program Managers, and Office of Naval Research (ONR) Department Directors, Division Directors and Program Officers **Estimated Time: 2 – 3 hours** Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 60 days of assignment.	**BIOMEDICAL FOCUS** 1. History & Ethical Principles 2. Defining Research with Human Subjects – SBR 3. SBR for Biomedical Researchers 4. Records –based Research 5. Genetic Research 6. Research with Protected Populations – Overview 7. Group Harms - Research with culturally or medically vulnerable groups 8. Privacy & Confidentiality – SBR 9. Conflict of Interest 10. Department of the Navy HRPP Module **SOCIAL-BEHAVIORAL RESEARCH** 1. History & Ethical Principles – SBR 2. Defining Research with Human Subjects – SBR 3. Assessing Risks – SBR 4. Records-based Research 5. Research with Protected Populations – Overview 6. Group Harms - Research with culturally or medically vulnerable groups 7. Privacy & Confidentiality – SBR 8. Conflict of Interest 9. Department of the Navy HRPP Module for COs	**Continuing training requirement: 3 hours every 3 years** Options: 1. CITI Program: 3 modules of your choice from refresher modules or other modules you have not taken 2. Three (3) hours of equivalent continuing training

Research Role	Initial Training	Continuing Training
3. Investigators, Key Research Personnel & Medical Monitors **Estimated Time: 4 – 6 hours** Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. All investigators, key research personnel (principal investigators, associate investigators, and all research personnel listed in the protocol), and medical monitors must complete the initial training requirement prior to submitting new research protocols for review. 3. If associate investigators, key research personnel, or medical monitors have not completed the initial training requirement, new research protocols will be accepted for review, but final approval will be	**BIOMEDICAL FOCUS** 1. History & Ethical Principles 2. Defining Research with Humans - SBR 3. Basic IRB Regulations & Review Process 4. Informed Consent 5. SBR for Biomedical Researchers 6. Assessing Risks – SBR 7. Records-based Research 8. Genetic Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Privacy and Confidentiality - SBR 13. FDA-regulated research 14. Conflicts of Interest 15. Hot Topics – No Quiz 16. Department of the Navy HRPP Module **SOCIAL-BEHAVIORAL FOCUS (SBR)** 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research 7. Research with Protected Populations – Overview 8. Group Harms - Research with culturally or medically vulnerable groups 9. Internet Research – SBR 10. Privacy and Confidentiality – SBR 11. Conflicts of Interest 12. Hot Topics – No Quiz 13. Department of Navy HRPP Module	**Continuing training requirement: 6 hours every 3 years** Options: 1. CITI Program: 6 modules of your choice from refresher modules or other modules you have not taken 2. Six (6) hours of equivalent continuing training CONTINUED ON NEXT PAGE

withheld until the training requirement has been met. Associate investigators, key research personnel, and medical monitors shall not participate in research activities until the initial training requirement has been met. 4. Investigators conducting research with pregnant women, children, prisoners, workers, students, or employees must complete the related modules.		

Research Role	Initial Training	Continuing Training
4. Scientific Review: Chair, Members, and Reviewers **Estimated Time: 1 hour** Note: Individuals serving in several roles must complete the most comprehensive requirements.	Each institution must determine its training requirements for these individuals and describe the requirements in its policies and procedures. The DON HRPP recommends the following modules: 1. History and Ethical Principles 2. Defining Research with Human Subjects 3. Department of the Navy HRPP Module	

Research Role	Initial Training	Continuing Training
5. Institutional Review Board (IRB) Chairs, Vice Chairs and Members **Estimated Time: 4 – 6 hours** Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete their initial training requirement prior to reviewing and voting on research protocols.	**BIOMEDICAL FOCUS** 1. History & Ethical Principles 2. Defining Research with Humans - SBR 3. Basic IRB Regulations & Review Process 4. Informed Consent 5. SBR for Biomedical Researchers 6. Assessing Risk – SBR 7. Records-based Research 8. Genetic Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Research with Prisoners – SBR 13. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module **SOCIAL-BEHAVIORAL FOCUS (SBR)** 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research 7. Research with Protected Populations – Overview 8. Group Harms - Research with culturally or medically vulnerable groups 9. Internet Research – SBR	**Continuing training requirement:** **6 hours every 3 years** Options: 1. CITI Program: 6 modules of your choice from refresher modules or other modules you have not taken 2. Six (6) hours of equivalent continuing training CONTINUED ON NEXT PAGE

	10. Privacy and Confidentiality – SBR 11. Research with Prisoners – SBR 12. Research with Pregnant Women 13. Research with Children - SBR 14. Conflicts of Interest 15. IRB Member 16. Hot Topics – No Quiz 17. Department of Navy HRPP Module	

Research Role	Initial Training	Continuing Training
6. HRPP (including legal counsel directly supporting the HRPP) & IRB staff **Estimated Time: 4 – 6 hours** Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions.	**BIOMEDICAL FOCUS** 1. History & Ethical Principles 2. Defining Research with Humans - SBR 3. Basic IRB Regulations & Review Process 4. Informed Consent 5. SBR for Biomedical Researchers 6. Assessing Risk – SBR 7. Records-based Research 8. Genetic Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Research with Prisoners – SBR 13. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module **SOCIAL-BEHAVIORAL FOCUS** 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research 7. Research with Protected Populations – Overview 8. Group Harms - Research with culturally or medically vulnerable groups	**Continuing training requirement:** **6 hours every 3 years** Options: 1. CITI Program: 6 modules of your choice from refresher modules or other modules you have not taken 2. Six (6) hours of equivalent continuing training. CONTINUED ON NEXT PAGE

	9. Internet Research – SBR 10. Privacy and Confidentiality – SBR 11. Research with Prisoners – SBR 12. Research with Pregnant Women 13. Research with Children - SBR 14. Conflicts of Interest 15. IRB Member 16. Hot Topics – No Quiz 17. Department of the Navy HRPP Module	

Research Role	Initial Training	Continuing Training
7. Research Coordinators, Clinical Coordinators, Study Coordinators & Research Administrators **Estimated Time: 4 – 6 hours** Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions.	**BIOMEDICAL FOCUS** 1. History & Ethical Principles 2. Defining Research with Humans - SBR 3. Basic IRB Regulations & Review Process 4. Informed Consent 5. SBR for Biomedical Researchers 6. Assessing Risk – SBR 7. Records-based Research 8. Genetic Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Research Involving Pregnant Women 13. Research Involving Minors 14. Research Involving Children- SBR 15. Privacy & Confidentiality – SBR 16. Workers as Research Subjects 17. FDA-regulated research 18. Conflicts of Interest 19. Hot Topics – No quiz 20. Department of the Navy HRPP Module **SOCIAL-BEHAVIORAL FOCUS** 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research 7. Research with Protected Populations – Overview 8. Group Harms - Research with culturally or medically vulnerable groups 9. Internet Research – SBR 10. Privacy and Confidentiality – SBR	**Continuing training requirement:** **6 hours every 3 years** Options: 1. CITI Program: 6 modules of your choice from refresher modules or other modules you have not taken 2. Six (6) hours of equivalent continuing training. CONTINUED ON NEXT PAGE

	11. Research with Pregnant Women 12. Research with Children - SBR 13. Conflicts of Interest 14. Hot Topics – No Quiz 15. Department of the Navy HRPP Module	

Research Role	Initial Training	Continuing Training
8. Research Support Personnel **Estimated Time: 1 hour** Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Research personnel are those who conduct clinical or research procedures; provide support to review committees; are responsible for access and release of private identifiable information, e.g., medical records personnel, information system personnel, individuals conducting procedures (laboratory, pharmacy, and radiology), legal counsel, grants and contracts personnel, privacy officers. 3. Individuals must complete the initial training requirements within 30 days of assignment to their positions.	Each institution must determine its training requirements for these individuals and describe the requirements in its policies and procedures. The DON HRPP recommends the following modules: 1. History and Ethical Principles 2. Defining Research with Human Subjects 3. Department of the Navy HRPP Module 4. Other modules, as appropriate, based on their role in research	

Research Role	Initial Training	Continuing Training
9. DON-supported Extramural Performers Note: The NIH web-based training program, "Human Participant Protections Education for Research Teams," is not adequate to meet DON HRPP training requirements.	All individuals conducting DON-supported extramural research must complete training that is equivalent to DON HRPP requirements prior to initiating work involving human subjects. a) If an institution does not have training requirements, its personnel must follow DON HRPP requirements (4 – 6 hours). Register as Principal Investigator. b) If an institution uses the CITI to meet its training requirements, its personnel also must complete the DON-specific module (15 minutes). Register as DON-supported Extramural Performer. c) If an institution's training requirement is not equivalent to DON requirements or CITI, its personnel must follow DON HRPP requirements (4 – 6 hours). Register as Principal Investigator.	All individuals conducting DON-supported extramural research must complete continuing training that is equivalent to DON HRPP requirements. a) If an institution does not have continuing training requirements, its personnel must follow DON HRPP requirements. b) If an institution uses the CITI to meet its continuing training requirements, its personnel also must complete the DON-specific module. c) If an institution's continuing training requirement is not equivalent to DON requirements or CITI, its personnel must follow DON HRPP requirements.

Department of Navy Human Research Protection Program
Continuing Education and Training Options

Individuals may choose continuing training from among the following options. This list is not meant to be all encompassing.

1. CITI Continuing Training Modules (see enclosure (1)).

2. The following organizations and agencies, among others, sponsor programs that meet DON HRPP continuing training requirements.

   a. DON HRPP
   b. Department of Defense, U. S. Army and U. S. Air Force
   c. Applied Research Ethics National Association (ARENA)
   d. Society of Research Administrators (SRA) International
   e. Office of Research Integrity (ORI)
   f. Office of Human Research Protections (OHRP)
   g. Food and Drug Administration (FDA)
   h. Public Responsibility in Medicine and Research (PRIM&R)
   i. Other institution's programs

3. The Poynter Center, Kennedy Institute, among others, sponsor courses, ethics symposia, and seminars that meet the continuing training requirement.

4. Several professional journals provide home-study programs.

5. Book: *Protecting Study Volunteers in Research*, Cynthia Dunn, M.D. and Gary Chadwick, PharmD., M.P.H., C. I. P. Continuing education credits for physicians, nurses, and other health-care professionals are available.